DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-677 / S-131

Baxter Healthcare Corporation
Route 120 and Wilson Road; RLT-10
Round Lake, IL 60073

Attn: Marcia Marconi
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated March 19, 2003, received March 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 0.9% Sodium Chloride Injection, USP in Plastic Container (PL 146).

This supplemental new drug application provides for an alternate sterilization process for the 50 and 100 mL Quad-Pack Mini-Bag Configuration.

We have completed our review of this supplemental new drug application and it is approved effective on the date of this letter.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lisa Malandro, Regulatory Project Manager, at (301) 827-7407.

Sincerely,

{See appended electronic signature page}

Mamta Gautam-Basak, Ph.D.
Chemistry Team Leader for the
Division of Metabolic and Endocrine Drug Products, (HFD-510)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Mamta Gautam-Basak
7/17/03 07:56:57 AM
Approved